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| 09/856,725 | 06/21/2001 | Jun Ueki | 0760-0290P | 3445 |
| 2292 | 7590 | 03/11/2004 | EXAMINER | |
| BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747 | | | KALLIS, RUSSELL | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1638 | |

DATE MAILED: 03/11/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/856,725

Applicant(s)

UEKI ET AL.

Examiner

Russell Kallis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 December 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 6-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 6-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

Claims 4-5 are cancelled and Claims 10-11 are added. Claims 1-3 and 6-11 are pending and examined.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of claims 1-9 under 35 U.S.C. 101 is withdrawn in view of Applicant's amendments.

The rejection of Claims 1-2 and 6 under 35 U.S.C. 102 is withdrawn in view of Applicant's amendments and arguments.

Claim Rejections - 35 USC § 112

Claims 2-3 and 7-9 remain and new Claims 10-12 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is maintained for the reasons of record set forth in the Official action mailed 6/9/2003. Applicant's arguments filed 12/8/2003 have been fully considered but they are not persuasive.

Applicant asserts that the amendments to the claims only recite subject matter that is described in the specification (response page 7). Applicant has not described a representative number of sequences that would have not less than 95% sequence identity to SEQ ID NO: 1.

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Further, the recitation of stringency conditions without any description of a sequence that would bind to SEQ ID NO: 1 under those conditions also does not meet the guidelines for written description.

Claims 2-3 and 7-9 remain rejected and new Claims 10-12 are under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for SEQ ID NO: 1 and SEQ ID NO: 2, does not reasonably provide enablement for a nucleic acid fragment of SEQ ID NO: 1 having one or more nucleotides substituted, deleted, inserted or added, or a part thereof; a nucleic acid fragment having not less than 70% sequence identity to SEQ ID NO: 1; a nucleic acid fragment that hybridizes to SEQ ID NO: 1 under conditions of unspecified stringency. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. Applicant's arguments filed 12/8/2003 have been fully considered but they are not persuasive.

This rejection is maintained for the reasons of record set forth in the Official action mailed 6/9/2003. Applicant's arguments filed July 1, 2002 have been considered but are not deemed persuasive.

Applicant asserts that the amendments to the claims fully enable the claims (response page 7). Applicant has not addressed the Examiner's rejection of nucleic acid sequences having a sequence identity other than that of SEQ ID NO: 1 or 2 or the rejection of sequences that hybridize to SEQ ID NO: 1 under unspecified stringency conditions. Further, the recitation of 6XSSC, 0.5% SDS and 50-65°C does not overcome the enablement rejection because those conditions would allow for non-specific hybridization and would retrieve nucleic acid sequences that would have no enhancer or promoter activity and require undue trial and error

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experimentation to eliminate non-functional embodiments. Furthermore, any sequence having 95% sequence identity to SEQ ID NO: 1 would also require undue trial and error experimentation to make, clone and test those non-exemplified sequences for increased activity of a down stream coding sequence in a transformed plant.

Claims 1, 3, 7-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. All dependent claims are included in the rejection.

Applicant asserts that the use of the term structural gene is well defined in the art and that the rejection is improper. As stated in the previous office action “gene” can be construed to have several meanings.

In Claim 1 and Claim 8, “gene” is indefinite. There is not a standard definition for this term, i.e., a gene can denote the coding region of an amino acid sequence or a gene can be defined as containing regulatory elements operably linked to the coding polynucleotide sequence encoding an amino acid sequence. If appropriate, the term “polynucleotide encoding a protein of interest” can be used to denote nucleic acid molecules that encode a polypeptide. All subsequent recitations of “gene” are also rejected. Further, “structural gene” does not indicate whether the promoter is operably linked to said “structural gene”, i.e. included as a part of a promoter-structural gene construct or is only influencing the expression of said “structural gene” from a distance.

In Claims 1, 3, 7, 8 and 9, “increases” or “increased”, is a relative term lacking in comparative basis.

Claim Rejections - 35 USC § 102

Claims 3 and 7-9 remain and new Claim 10 is rejected under 35 U.S.C. 102(b) as being anticipated by Ueki J. *et al.*, Plant Cell and Physiology, June 1999; Vol. 40, No. 6; pp. 618-623.

The claims are broadly drawn to an isolated nucleic acid comprising a nucleotide sequence, the complement thereof which hybridizes with SEQ ID NO: 1 under conditions of low stringency, 6XSSC, 0.5% SDS and 50-65°C that drives expression of a downstream structural gene, and a method thereof.

Ueki teaches the first intron of the rice PDL gene (i.e. an isolated nucleic acid comprising a nucleotide sequence, the complement thereof which hybridizes with SEQ ID NO: 1 under conditions of low stringency, 6XSSC, 0.5% SDS, and 50-65°C), increasing the expression of GUS, a downstream structural gene, in transformed rice cells on page 619 column 2, first paragraph of Results and in Figure2A on page 620 column 2. The reference teaches all the limitations of Claims 1-8.

Applicant asserts that the Ueki reference fails to anticipate the present invention because the sequence of intron 1 and intron 2 are utterly different (response page 10). Applicant provides no art or data to back this assertion. The claims are broadly drawn to nucleic acid sequences that would hybridize to SEQ ID NO: 1 under low stringency conditions as recited in the amended Claim 3. The permissive hybridization conditions recited in amended Claim 3 would allow for hybridization of the two introns, especially so since the claim does not recite any wash conditions.

Applicant asserts that the intron of SEQ ID NO: 1, i.e. the second intron, is superior to the first intron taught by Ueki in enhancing activity of GUS, and thus the reference fails to

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suggest the use of the second intron or anticipate the present invention (response page 10). The claims are not drawn to any particular level of expression of a downstream coding region and since the claims are broadly drawn with respect to sequences that hybridize to SEQ ID NO: 1 the Ueki reference reads upon the invention of Claim 3.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 3, 7-9 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ueki J. *et al.*, Plant Cell and Physiology, June 1999; Vol. 40, No. 6; pp. 618-623 in view of Tanaka A. *et al.* Nucleic Acids Research, 1990; Vol. 18, No. 23, pp.6767-6770.

Applicant broadly claims a plant transformed with a recombinant vector comprising a nucleic acid sequence that hybridizes to SEQ ID NO: 1 under hybridization conditions of 6XSSC, 0.5% SDS, and 50-65°C that increases expression of a structural downstream gene.

The teachings of Ueki are discussed *supra*.

Ueki does not teach transformation and regeneration of rice.

Tanaka teaches increased expression of GUS in rice transformed with a construct comprising a dicot intron, CaMV 35S promoter and GUS.

It would have been *prima facie* obvious at the time of Applicant's invention to modify the invention of Ueki to include a method for transforming rice cells and regenerating transformed rice plants from transformed rice cells. One would have been motivated by the

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success of Tanaka in both transforming rice and regenerating whole plants and in increasing foreign gene expression by including an intron as an enhancer of CaMV 35S promoter activity driving GUS. One of skill in the art would have been motivated by the teachings of both Tanaka and Ueki that the intron regions of plant genes are valuable materials for genetic engineering of gene expression in plants, and that one would have had a reasonable expectation of success of expressing genes in transformed rice plants.

All Claims are rejected.

Claims 1-2, 6 and 10-11 are deemed free of the prior art given the failure of the prior art to teach or suggest an isolated nucleic acid having no less than 95% sequence identity to SEQ ID NO: 1 that increases the activity of a downstream structural coding region, a transformed plant therewith, and a method thereof.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Russell Kallis whose telephone number is (571) 272-0798. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (571) 272-0804. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Russell Kallis Ph.D.
March 3, 2004

Phuong T. Bui
3/8/04

PHUONG T. BUI
PRIMARY EXAMINER